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09/582,182	10/26/2000	Alfred Von Schuckmann	06275/209001	8134

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EXAMINER

RADEMACHER, MARK A

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

HCT

Office Action Summary

Application No.

09/582,182

Applicant(s)

VON SCHUCKMANN ET AL.

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-53 is/are rejected.
- 7) ☒ Claim(s) 48 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION***Preliminary Amendment***

The Office acknowledges and has entered the preliminary amendment filed on June 22, 2000 in which claims 1-27 were canceled and claims 28-53 were added. Claims 28-53 are pending.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Germany on December 22, 1997 (DE19757207.3 and DE19757208.1). It is noted, however, that applicant did not file of the DE197208.1 application with the International Bureau, and has not filed a certified copy as required by 35 U.S.C. 119(b).

Claim Objections

Claim 48 and 49 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 48 depends from claim 28, which appears to be directed to a suction tube. However, neither claim 48, nor its dependent claim 49 recite additional features of the suction tube. Claims 50-53 are objected to because they depend from claims 48 and 49.

Claim 47 is objected to because of the following informalities: In line 2 of claim 47, the reference character I 17' appears to be a typographical error. It appears that the reference character should be 117'. Appropriate correction is required.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether independent claim 28 is directed to a suction tube or the combination of a suction tube and a medicament-containing blister having a covering.

Similarly, it is unclear whether the dependent claim 48 is directed to the combination of a suction tube and an inhaler, as an inhaler is not positively recited in the claim. Dependent claims 29-53 are rejected because they incorporate the indefiniteness of their parent claim(s). Other claims including claim 46 that include language referring to both blisters containing powdered medicament and a suction tube having particular structural features are rejected for the same reasons. ✓

In line 4 of dependent claim 29, the applicant recites "before the bearing surface of the at least one ram blade contacts the covering film of the blister". However, parent claim 28 includes the language "the bearing surface is in the form of a ram blade". ✓

These recitations appear to be inconsistent because the parent claim indicates that the bearing surface is the ram blade, whereas the dependent claim indicates that the bearing surface is a feature of the ram blade. Accordingly, the language in these claims is indefinite. Claim 30 is similarly indefinite. |

In addition, claim 37 recites the limitation "wherein each ram blade" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 28

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recites only one ram blade. Depending claims 38-41 are also rejected because they incorporate the antecedent deficiency of claim 37.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-34, 36, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,566,859 to *Willis et al (Willis)*.

Giving claim 28 its broadest reasonable interpretation, claim 28 recites a suction tube comprising an elongate body that includes an inlet section including an inlet at one end thereof, an outlet section including an outlet capable of acting as a mouth piece at the other end of the elongate body, and an inhalation channel providing fluid communication between the inlet and the outlet. The inlet section includes a cutting assembly including one cutting blade that includes a cutting edge capable of making a cut in a covering film of a blister and at least one bearing surface for bearing on a covering film of a blister and pushing the covering into the cavity of the blister, wherein the cutting blade extends across the inlet and the bearing surface is in the form of a ram blade. The broadest reasonable interpretation of claim 28 does not require a blister having a powdered medicament or the like, but simply a suction tube having the structure clearly positively recited therein.

Willis discloses a foil piercing and clearing nozzle. The structure described in *Willis* incorporates all of the features positively recited in claim 28. Specifically *Willis*

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discloses an elongate body (the inner cylindrical portion shown at the top of FIG 3 of *Willis*) that includes an outlet portion having an outlet and an inlet portion having an outlet that may be used as a mouthpiece, an inlet portion having an inlet and an inhalation channel in fluid communication therebetween. See FIG 2 and 3 of *Willis* for example. *Willis* discloses that the inlet includes a cutting assembly (piercing blade 24) including at least one cutting blade (piercing means 16) and at least one bearing surface in the form of a ram blade (inward facing surface of flange 34). As shown in FIG 2 of *Willis*, the cutting piercing means extends across the inlet. Moreover, the bearing ram blade engages the frangible seal and biases the seal out of the flow path. See *Willis* column 4, lines 41-44 for example.

With respect to claims 29-34, 36 and 46-48, *Willis* discloses all of the additional features recited therein:

Claim 29 - FIG 3 of *Willis* shows that the cutting blade (piercing means 16) extends axially forward of the bearing surface of the at least one ram blade (flange 34) which would make the structure capable of partly cutting the covering film of a blister before the bearing surface contacts the blister;

Claim 30 - FIG 3 of *Willis* which shows a cutting blade that extends axially forward of the bearing surface of the at least one ram blade, which is also capable of cutting the covering film of a blister before the bearing surface of the ram blade contacts the covering film;

Claim 31 - FIG 3 shows that the inlet is substantially co-axial with the longitudinal axis of the body;

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Claim 32 - FIG 3 also shows that the cutting blade is substantially co-axial with the longitudinal axis of the body;

Claim 33 - FIGS 2 and 3 shows that the cutting blade (16) converges to at least one point;

Claim 34 - FIGS 2 and 3 shows that the cutting blade (16) includes first and second sections that taper to a cutting point;

Claim 36 - FIGS 2 and 3 show that the cutting blade (16) is substantially planar;

Claim 46 - FIG 7 shows that the axial position of the inlet is such that it is capable locating the inlet section is located below a surface that defines the cavity of a blister;

Claim 47 - FIG 3 shows that the inlet section of the foil piercing and clearing nozzle includes a shoulder (annular groove 36) that is capable of being located at the upper surface of the blister; and

Claim 48 - because the applicant does not positively recite additional inhaler structure the foil piercing and clearing nozzle disclosed in *Willis* includes all of the features of claim 48. See the discussion of claim 28 above.

Allowable Subject Matter

Assuming applicant overcomes the applicable rejections under Section 112, second paragraph, claims 35, 37-45, and 49-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PCT international publication WO 97/40876 discloses an inhaler including many of the features in the present application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR
November 15, 2002


GLENN K. DAWSON
PRIMARY EXAMINER